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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	18

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,420	YOSHINAGA ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-7,9,11,13-18 and 24-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10,12 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment, filed 10/7/02 (Paper No. 15), is acknowledged.
Claims 1-42 *are pending.*

2. Applicant's election of Group IV (claims 8, 10, 12 and 19-23) with a species election of SEQ ID NOS 12 and 17 (encoded by SEQ ID NOS:11 and 16) in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-7, 9, 11, 13-18 and 24-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Although the instant claims reciting SEQ ID NOS:12 and 17 are anticipated as set forth below, in the interest of compact prosecution, the search has been extended to include SEQ ID NO:7 (encoded by SEQ ID NO:6).

Claims 8, 10, 12 and 19-23 *are under consideration in the instant application.*

Sequence Compliance

3. Sequence compliance: Applicant's provision of a corrected CRF, Sequence Listing, and Statement that the contents are identical on 10/07/02 (Paper No. 15), is acknowledged. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Drawings

4. The formal drawings submitted 10/07/02 have been approved by the Draftsman.

5. Applicant is reminded to amend the Brief Description of the Drawings to reflect the numbering used in the Figures and to describe each individual panel.

For example, "Figure 1" should read -- Figures 1A.1-1B --.

In addition, the description of the panel "B" for Figure 1, as amended in Paper No. 10, received 5/17/02, does not describe the material of panel "B" other than to indicate "B) (SEQ ID NOS:3, 4 & 5)..."

Appropriate correction is required.

IDS

6. It is noted that no IDS appears to have been filed in the instant application.

Specification

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

In addition, Applicant should avoid the use of "novel" in the title, as patents are presumed to be novel and unobvious.

It is suggested that Applicant amend the title to read -- B7-RP1 POLYPEPTIDES --.

8. The abstract is objected for failure to clearly include the elected invention. A new abstract is required which includes the subject matter claimed. In addition, Applicant should avoid the use of "novel" in the abstract.

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Objections

10. Claims 8, 10 and 19-23 are objected to as being dependent on non-elected claims. Any claim which depends from a non-elected claim should be re-written as an independent claim, or to depend from an elected claim. Appropriate correction is required.

11. Claim 12 is objected to because of the following informalities:
in lines 1-2, the definite article "the" is recited in the phrase "comprising the amino acid sequence selected from the group consisting of" when it appears that the indefinite article -- an -- is appropriate;
in line 8, claim 12 recites "amino terminus at residues 47" when it appears that the singular -- residue -- is appropriate.
Appropriate correction is required.

12. Claims 19, 20 and 22 are objected to for reciting "the polypeptide of Claims 9, 10, 11 or 12". It appears that the singular -- claim -- is appropriate in view of the definite article and the requirement that a claim must depend from multiple claims in the alternatively only. Appropriate correction is required.

Claim Rejections - 35 USC § 112 first paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 8, 10, 12 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The specification discloses that the polypeptides of SEQ ID NO:12 and SEQ ID NO:17 are two forms of a human B7-RP1 polypeptide; and that SEQ ID NO:7 is a mouse B7-RP1 polypeptide.

The claims recite:

A) "variant" language, including a "derivative" of a B7-RP1 polypeptide (claim 20) and "percent identity variants" (as set forth in non-elected claim 2 from which elected claims 8 and 10 depend;
B) polypeptides comprising "fragments";
C) "allelic variants" and "alternative splice variants" of (nucleic acids encoding) B7-RP1 polypeptides; and
D) "an ortholog" of a B7-RP1 protein or protein variant.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the following reasons:

A) "Variants":

The claims recite a genus of polypeptides but do not require that the instant polypeptides share any testable functional activity, a feature deemed essential to the instant invention. Applicant has disclosed two human and one mouse B7-RP1 polypeptide, and thus has disclosed only a limited number of "variants". In the absence of a particular testable function and some structural basis for that function that must be maintained by the members of the genus, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

B) "Polypeptides Comprising Fragments":

Fragment language that encompasses open (comprising) claim language permits unidentified flanking sequence to be added to the recited subsequence of a particular SEQ ID NO and so does not allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Fragments which comprise unidentified flanking sequence or have variation within their sequence thus do not meet the written description requirement. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (id at 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (id at 1116.).

C) "Allelic Variants" and "Splice Variants":

The term "allelic variants" encompasses any gene that occurs at essentially the same locus in the genome as the reference gene, as disclosed in the specification as-filed on page 25, lines 10-13. Similarly, a "splice variant" is a reference to an alternate form of a nucleic acid created by alternate processing of intronic sequence (e.g., specification page 25 at lines 14-17). As noted supra, the instant claim language is considered with respect to polypeptides encoded by these variant nucleic acid sequences. However, there is insufficient written description in the specification of allelic and splice variants of B7-RP1. Although the specification does provide alternate forms of human B7-RP1 polypeptides that may be encoded by different splice variants, there does not appear to be any description of the alternately processed transcripts. Neither does there appear to be adequate description of the locus to show that Applicant was in possession of polypeptides encoded by 'allelic variants". Further, it is noted that allelic variants do not necessarily encode proteins having the same function. For example, Voet et al. (In Biochemistry. John Wiley & Sons. 1990, Vol.1, pages 126-128, and page 230) teaches that allelic variation in the β subunit of hemoglobin results in drastically different functions, even though the proteins share a high level of sequence and structural homology.

The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991). Thus the terms "allelic variant" and "splice variant" fail to provide a structure for which a function can be correlated, and in the absence of additional support in the specification as filed, these terms do not meet the written description provision of 35 U.S.C. 112, first paragraph.

D) An "ortholog" of a B7-RP1 polypeptide:

The specification discloses that an ortholog of a B7-RP1 protein may be isolated from *any* species (page 43, lines 23-26). Thus the genus recited is very large. As noted supra the specification discloses only human and mouse forms of B7-RP1 polypeptides. Thus the specification provides at most two members of the instant extensive genus. However, in University of California v. Eli Lilly and Co., 39 USPQ2d 1225 (Fed. Cir. 1995); the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The Court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. Therefore, the specification does not provide sufficient written support for the genus of polypeptides that includes any "ortholog" of a B7-RP1 polypeptide, irrespective of the inclusion of functional limitations. A description of what a material does, rather than of what it is, usually does not suffice. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

The specification therefore fails to provide an adequate written description of the above noted claim limitations.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Alternatively, Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

15. Claims 8, 10, 12 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

B7-RP1 polypeptides "consisting of" or "comprising" SEQ ID NO:7, 12 or 17;
B7-RP1 polypeptides encoded by nucleic acids "consisting of" or "comprising" SEQ ID NO:6, 11 or 16;
fragments of SEQ ID NO:7, 12 or 17 in which the claim language clearly limits the fragments to *sub*sequence of SEQ ID NO:7, 12 or 17;
"derivatives" which are clearly limited to chemical derivatives (e.g., as recited in claim 21);
fusion polypeptides defined as set forth above and fused to a heterologous amino acid sequence; and
polypeptides having only limited deviation from a reference sequence (e.g., a polypeptide 95% identical over the full length of SEQ ID NO:7) AND having a testable function supported in the specification as filed (and priority documents);

does not reasonably provide enablement for

A) "variant" language, including a "derivative" of a B7-RP1 polypeptide (claim 20) and "percent identity variants" (as set forth in non-elected claim 2 from which elected claims 8 and 10 depend;
B) polypeptides comprising "fragments";
C) "allelic variants" and "alternative splice variants" of (nucleic acids encoding) B7-RP1 polypeptides; and
D) "an ortholog" of a B7-RP1 protein or protein variant.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification discloses that the polypeptides of SEQ ID NO:12 and SEQ ID NO:17 (encoded by SEQ ID NOS:11 and 16, respectively) are two forms of a human B7-RP1 polypeptide; and that SEQ ID NO:7 (encoded by SEQ ID NO:6) is a mouse B7-RP1 polypeptide. The specification also discloses (e.g., Example 8) on pages 81-83 that B7-RP1 is, along with CRP1, part of a costimulatory receptor-ligand pair.

A) "Variant Polypeptides":

The state of the art at the time the invention was made recognized that even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) showed that any of a variety of single amino acid changes can alter or abolish the ability of the CTLA4 to interact with its ligands CD80 and CD86 (B7-1 and B7-2) (e.g., summarized in Table 2). The variation in function among "B7-like" polypeptides is further emphasized by the teachings of Coyle et al. (Nature Immunol. 2:203-209 2001) who show that the B7-like family members have distinct expression patterns *and distinct functions* , even though they share certain conserved amino acid residues and domain structure (see in particular Figures 2 and 3). Given the extensive variation permitted by the instant claim language, the skilled artisan would not reasonably expect such "variant" polypeptides to have the same function as the instantly recited SEQ ID NOS, particularly when the family of B7-like proteins was known to have variable function.

It is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. The specification does not appear to provide sufficient guidance as to which residues should or should not be changed to preserve any particular function. Although the specification does provide working examples of human and mouse B7-RP1 polypeptides, the variation permitted by the instant claim language is extensive. Consequently, the experimentation left to those skilled in the art to determine which "variant" sequences would still result in polypeptides having the same function as a the human and mouse B7-RP1 polypeptides disclosed in the specification as filed is unnecessarily, and improperly, extensive and undue.

It is suggested that Applicant limit the claims to variant nucleic acids sequences having only limited variation (e.g. 95% identity) *over the full length* of the sequence, AND *possessing testable functional activity* supported in the specification and priority documents.

B) "Fragments Comprising":

The instant claims recite in various forms polypeptides comprising "fragments" of a certain number of amino acid residues of the various SEQ ID NOS (or encoding nucleic acids). "Comprising" language opens the claim up to the inclusion of additional residues of undisclosed identity and number flanking the recited "fragment". The skilled artisan can make fragments *limited* to *sub*sequences of the individual SEQ ID NOS without undue experimentation. However, before the skilled artisan can make polypeptides comprising "fragments" with additional flanking sequence, guidance is required with respect to the identity of those flanking sequences. In the instant case however, the specification does not appear to provided this needed guidance. Therefore the scope of the instant claims encompassing "fragments comprising" does not appear to be commensurate with the enablement provided by the instant disclosure.

C) "Allelic Variants" and "Splice Variants":

The term "allelic variants" encompasses any gene that occurs at essentially the same locus in the genome as the reference gene, as disclosed in the specification as-filed on page 25, lines 10-13. Similarly, a "splice variant" is a reference to an alternate form of a nucleic acid created by alternate processing of intronic sequence (e.g., specification page 25 at lines 14-17). As noted supra, the instant claim language is considered with respect to polypeptides encoded by these variant nucleic acid sequences, but the specification does not appear to provide an adequate written description of "allelic variants" or "splice variants" of the instant sequences; thus the specification fails to provide sufficient guidance as to how to make these sequences.

In addition, neither allelic variants nor splice variants necessarily encode proteins having the same function. For example, Voet et al. (In Biochemistry. John Wiley & Sons. 1990, Vol.1, pages 126-128, and page 230) teaches that allelic variation in the β subunit of hemoglobin results in drastically different functions, even though the proteins share a high level of sequence and structural homology. Thus even had the specification clearly taught how to make allelic or splice variants of the instant sequences, the skilled artisan still would not know how to use the polypeptides encoded by them. Consequently, the scope of claims reciting either "allelic variants" or "splice variants" does not appear to be commensurate with guidance provided in the specification as filed.

D) An "ortholog" of a B7-RP1 polypeptide:

The specification discloses that an ortholog of a B7-RP1 protein may be isolated from *any* species (page 43, lines 23-26). As noted supra the specification discloses only human and mouse forms of B7-RP1 polypeptides and fails to provide an adequate written description of any other "ortholog".

The specification also does not provide sufficient guidance as to how the skilled artisan may identify, without undue experimentation, any other ortholog. The state of the art recognized that identification of orthologous polypeptides required extensive experimentation in order to identify a candidate polypeptide from additional species (i.e., polypeptides with similar sequence) and then ascertain whether that polypeptide possessed functional similarities sufficient to justify it assignment as an ortholog of a polypeptide previously identified in another species. Thus the instant claims are essentially a wish to know the identity of any polypeptide which can be construed to be an "ortholog" of the instant B7-RP1 human and mouse polypeptides. It has been previously decided that claims recitations so broad do not provide sufficient guidance as to how to make and use the claimed invention. See Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

Thus with respect to the above noted claim limitations, each of which encompass considerable breadth and for each of which the specification provides only limited guidance; it would require undue experimentation of the skilled artisan to make and use such polypeptides; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claim Rejections - 35 USC § 112 second paragraph

16. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 12 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 and dependent claims 19-23 recite "an allelic variant" or "alternative splice variant" of a polypeptide. However, as was well known in the art and (e.g., as set forth in the specification on page 25 at lines 10-17), these terms refer to nucleic acids, not polypeptides. Therefore the metes and bounds of the instant claim language is unclear.

For examination purposes, the claim will be interpreted as reciting polypeptides encoded by these "variant" nucleic acid sequences.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections – 35 U.S.C. §§ 102 and 103

18. It is noted that the instant claim language with respect to the polypeptide of SEQ ID NO:7 (322 amino acid form of mouse B7-RP1, encoded by SEQ ID NO:6) and the polypeptide of SEQ ID NO:12 (288 amino acid form of human B7-RP1, encoded by SEQ ID NO:11) appears to supported in parent USSN 09/244,448 (filed 2/3/99).

The instant claim language with respect to the polypeptide of SEQ ID NO:17 (302 amino acid form of human B7-RP1, encoded by SEQ ID NO:16) does not appear to be supported in parent USSN 09/244,448 (filed 2/3/99), but does appear to be supported in parent USSN 09/264,527 (filed 3/8/99).

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

20. Claims 8, 10, 12 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Ishikawa et al (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999).

Ishikawa et al. teach gene number KIAA0653, and that the sequence information for the cDNA and the protein product of KIAA0653 is available under accession number AB014553 (see entire document, but especially Table 1, first column). Ishikawa et al. also teach that the protein product of KIAA0653 was produced by in vitro translation (see comments in Section 2.1 on page 169 regarding original screening method) and that the 558 amino acid open reading frame encodes a protein of apparent molecular mass of 60 kDa (Table 1).

Ishikawa et al. teach that the KIAA0653 has homology to CD80, the original member of the B7 family of co-stimulatory proteins (e.g. see Table 2, page 175).

The protein product of KIAA0653 encompasses the entire amino acid sequence set forth in SEQ ID NO:12. Thus the protein product of KIAA0653 is a polypeptide comprising:

the amino acid sequence as set forth in SEQ ID NO:12;

the mature amino acid sequence as set forth in SEQ ID NO:12 comprising a mature amino terminus at any one of residues 19, 20, 21, 22, 24 or 28; and

a fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 12.

The protein product of KIAA0653 also encompasses the amino acid sequence as set forth in SEQ ID NO:17, except for the final 2 amino acids. Thus the protein product of KIAA0653 is also a polypeptide comprising a fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 17.

The protein product of KIAA0653 is an human polypeptide that is an ortholog of the polypeptide of SEQ ID NO:7.

Given that KIAA0653 is a nucleic acid that includes the coding region of SEQ ID NO:11 and comprises a fragment of the nucleic acid sequence of SEQ ID NO:16; the protein product of KIAA0653 also meets the limitations of instant claims 8 and 10.

KIAA0653 is an encoding nucleic acid that is an allelic variant and/or splice variant of instant SEQ ID NOS:11 and 16. In addition, the protein product of KIAA0653 is also a "derivative" of the instantly recited polypeptides.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations would be inherent properties of the protein product of KIAA0653.

The reference teachings thus anticipate the instant claimed invention.

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999) in view of Linsley et al. (U.S. Pat. No. 5,580,756).

The claims are drawn to compositions comprising a B7-RP1 polypeptide, derivatives of said polypeptide that include polypeptides modified with a water-soluble polymer, and fusion polypeptides comprising a B7-RP1 polypeptide.

Ishikawa et al. have been discussed supra, and in brief, teach a B7 (CD80)-related polypeptide encoded by KIAA0653.

Ishikawa et al. do not teach derivatives of said polypeptide that include polypeptides modified with a water-soluble polymer, and fusion proteins comprising the encoded polypeptide. Ishikawa et al. also do not teach formulation of the polypeptide in a pharmaceutically acceptable carrier, adjuvant, stabilizer or anti-oxidant.

Linsley et al. teach the B7 (CD80) polypeptide and its characterization as a co-stimulatory protein (see entire document, e.g., "Summary of the Invention" at columns 3-4).

Linsley et al. teach formulation of the B7 polypeptide in pharmaceutically acceptable carriers (e.g. column 12, especially lines 27-37); and the production of derivatives of the B7 polypeptide (e.g., column 6, especially lines 31-45). Although derivitization of the B7 polypeptide with a water soluble polymer was not explicitly taught by Linsley et al., modification of polypeptides with water soluble polymers such as PEG was well known in the art at the time the invention was made and in common use to improve the solubility and half-life of the polypeptide of interest.

Further, Linsley et al. teach the production of fusion proteins of the B7 (CD80) polypeptide, including fusion proteins wherein the heterologous sequence is an IgG constant domain or fragment thereof (see entire document, but especially columns 26-31). Linsley et al. also teach the application of B7Ig fusion protein for characterization of the B7 protein's co-stimulatory effect on T cells and for detecting expression of the counter receptor for B7 (see entire document, but especially columns 29-36).

Given the identification of the polypeptide of Ishikawa as a CD80 (B7)-related polypeptide, the ordinary artisan at the time the invention was made would have found it obvious to make compositions comprising the polypeptide of Ishikawa, derivatives of said polypeptide that include polypeptides modified with a water-soluble polymer, and fusion polypeptides comprising the polypeptide of Ishikawa et al. and an IgG constant domain or portion thereof. The ordinary artisan at the time the invention was made would have been motivated to produce fusion proteins comprising the B7-related protein of Ishikawa in order to further characterize the B7-related protein, and in order to identify cell types expressing the counter-receptor of this B7-related protein. Given the detailed teaching of Linsley et al. regarding production of fusion proteins, including fusion proteins of the IgG constant domain or fragments thereof, and the teachings of the amino acid and cDNA sequence by Ishikawa et al.; the ordinary artisan at the time the invention was made would have had a reasonable expectation of successfully producing the instantly recited fusion proteins. Similarly, the ordinary artisan at the time the invention was made would have been motivated to covalently modify the polypeptide with a water soluble polymer such as PEG using techniques well-known in the art at the time the invention was made in order to improve the solubility characteristics and half-life of the polypeptide. Finally, the ordinary artisan at the time the invention was made would have been motivated to formulate the polypeptide or derivative or fusion protein thereof in a pharmaceutically acceptable carrier in order to assay the activity of the polypeptide in vitro and in vivo. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

23. No claim is allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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